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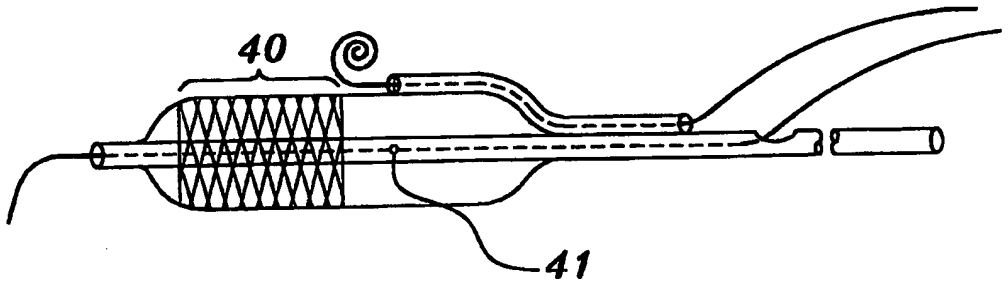

(57) Abstract

A dilation catheter has a distal guidewire exit located distal to a dilatation means and at least one additional proximally located positioning guidewire exit, the positioning guidewire exit located along the dilatation means. An oblique ended expandable stent is mounted around the dilatation means and used to treat bifurcated and sidebranched arteries and ostial lesions.

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AN APPLICATION CATHETER AND METHOD OF IMPLANTATION OF A STENT IN VASCULAR BIFURCATIONS, SIDE BRANCHES AND OSTIAL LESIONS

Technical Field

This invention relates to a stent and its implantation into blood vessels. More particular, it relates to a stent and an application catheter used to implant the stent into vascular bifurcations, SIDE BRANCHES and ostial lesions.

Background Art

Stents are prostheses to support the lumen of hollow organs, primarily to acutely maintain the lumen of blood vessels after mechanical interventions such as balloon angioplasty and to achieve a better long term result after such mechanical interventions. While implantation of stents into straight vessel segments poses little technical problems, implantation of stents into ostial lesions, sidebranches or into vessel bifurcations represents a challenge to the operator and carries increased risks of acute and long-term failure, in particular due to misplacement or imprecise placement.

In ostial lesions, the proximal end of the stent must be precisely placed at the ostium of the artery so that the stent is not protruding into the aortic lumen. In order to avoid the above risk, the stent is sometimes advanced too far into the artery causing the initial segment of the diseased ostium to remain unstented.

A similar problem exists with stenting of sidebranches and vessel bifurcations. For both situations, precision placement techniques are required for optimal results. However, the operator must rely on visual assessment during fluoroscopy with and without contrast injections. Contrast injections are of little help for stenting in ostial lesions, since opacification of the target artery is usually inadequate and identification of the aortic lumen and the ostial takeoff is very limited. In sidebranch and bifurcational lesions, precise placement is similarly difficult due to poor identification of the exact beginning of the sidebranch ostium and the often non-perpendicular nature of the plane of the sidebranch in relation to the axis of the major vessel. The beating heart makes maintaining of a catheter position with current techniques even

more difficult if not impossible.

The current invention offers a unique solution to the technical problems as described above.

Disclosure of Invention

A dilation catheter has a distal guidewire exit located distal to an inflatable balloon portion and at least one additional, more proximally located positioning guidewire exit; the at least one additional, more proximally located positioning guidewire exit located along the inflatable portion of the balloon or other expandable portion of dilatation catheter. An oblique ended expandable stent is mounted therearound and used to treat bifurcated and sidebranched arteries and ostial lesions.

Brief Description of Drawings

Figure 1A shows an improved dilatation catheter of the present invention;

Figure 1B shows an alternate embodiment of the improved catheter of the present invention;

Figure 1C shows yet another alternate embodiment of the improved catheter of the present invention;

Figure 1D shows yet even another alternate embodiment of the improved catheter of the present invention;

Figure 2A shows the improved catheter of the present invention having a stent mounted therearound;

Figure 2B shows a prior art stent having its end axis perpendicular to its longitudinal axis;

Figure 2C shows an oblique ended stent used with the catheter of the present invention;

Figure 3A shows a non-oblique ended stent in a bifurcated artery having a lesion formed thereupon which is not covered by the non-oblique ended stent;

Figure 3B shows a non-oblique ended stent in a bifurcated artery having a lesion formed thereupon which is covered by the non-oblique ended stent but permits an end of the stent to protrude into the main artery;

Figure 3C shows an oblique ended stent used in the present invention which is capable of covering the lesion but prohibits an end portion of the stent from protruding into the main

artery;

Figure 4A shows the improved catheter of the present invention being used to insert an oblique ended stent into a bifurcated artery;

Figure 4B shows the improved catheter of the present invention being used to insert an oblique ended stent, the catheter depicted outside an artery;

Figure 4C is a top plan view, partially in section, of the configuration depicted in Figure 4B showing the additional guidewire exit located along the balloon catheter;

Figure $5A_1$ shows a sinusoidal ring configuration of a stent used in the present invention;

Figure $5A_2$ shows a more detailed view of the Figure $5A_1$;

Figure $5B_1$ shows a non-expanded closed loop configuration used to form an oblique end of a stent in the present invention;

Figure $5B_2$ shows an expanded closed loop configuration used to form an oblique end of a stent in the present invention;

Figure $5C_1$ shows a non-expanded ratcheting band configuration used to form an oblique end of a stent in the present invention; and

Figure $5C_2$ shows an expanded ratcheting band configuration used to form an oblique end of a stent in the present invention

Best Mode for Carrying Out the Invention

A balloon catheter as used for vascular dilatation commonly has a balloon inflation channel along the whole length of a pliable shaft of the balloon catheter up to the beginning or the mid-portion of the balloon, and a so called regular guidewire channel through which the angioplasty guidewire is fed. The regular guidewire channel commonly exits at the distal end of the balloon catheter (very distal catheter tip). Depending on whether the regular guidewire channel is running through the whole length of the balloon catheter shaft and exiting proximally at the proximal end of the balloon catheter shaft or whether the guidewire channel is exiting via a side-exit proximal to the balloon (i.e., the regular guidewire channel being substantially shorter than the whole catheter

length), the balloon catheters are termed over the wire or mònorail balloon catheters.

In order to create a technique to assist to mechanically self-position an application catheter, in an ostial, sidebranch or bifurcational lesion, or to orient the application catheter to a certain direction within a 360 degree circumference of the vessel, the application catheter must have a mechanical means to limit its advancement beyond a certain point and/or to direct the application catheter to the desired target. This is realized, as seen in Figures. 1A - 1D, by an additional wire exit 11 located along an inflatable portion of a balloon catheter (or other expandable means) used for stenosis dilatation (within the distal and proximal end of the balloon catheter) or along the respective portion used for stenosis dilatation or stent, drug or radiation application of any other application catheter or located within a short portion of length (i.e., 1 - 30 mm) beginning just proximal to the functional segment of a stent application catheter or other application catheter of other therapeutics and extending proximally. Such wire exit 11 along the balloon segment as described above is referred to as the "extra distal wire exit 11" in any further description.

The extra distal wire exit 11 is the distal end of a wire channel 14 that may run along the whole length of the balloon catheter shaft and exit proximally (over the wire fashion) or the distal end of a wire channel 14 that is significantly shorter than the shaft of the catheter and therefore exits from the shaft at any location proximal to the balloon segment or the functional segment as described above. An extra guidewire 15 is threaded therethrough. Preferably, but not necessarily, the proximal exit of the extra wire channel 14 is within the distal half of the catheter so that easy monorail handling of such extra wire channel 14 and extra guidewire 15 is possible, as seen in Figure 1A. In further reference to Figure 1A, it is shown that the catheter has a distal tip 10 through which a regular guidewire 12 exits. A radiopaque marker 13 can be employed on the balloon catheter at the level of the additional wire exit. Figure 1C illustrates the exit point 30 of guide

wire 12.

It an alternate embodiment, the extra wire channel 14 merges with a regular guidewire channel 16 over a certain distance or its total length and may use the same proximal side exit 20 as the monorail guidewire channel, as seen in Figure 1B, or the same exit at its very proximal end.

In yet another alternate embodiment, as seen in Figure 1D, the additional proximal wire exit is located on the regular guidewire channel intermediately positioned between the entrance of the regular guidewire channel and the distal tip 10 of the catheter; the regular guidewire channel is mounted to the outside of the balloon or other inflation means. Thus, the regular guidewire channel and the extra wire channel are the same channel over a certain segment.

To insert the stent of the present invention using a monorail type balloon catheter for bifurcational (or sidebranch) dilatation and stenting, the preferred steps include: placing the guidewire 12 in the target artery (sidebranch); placing the extra guidewire 15 in the main artery; advancing the balloon catheter over guidewire 12 (placed in the target lesion) which is threaded through the distal opening of the guidewire channel 16 at the balloon catheter tip 10 and over the extra guidewire 15 (main artery), which is threaded through the extra distal wire exit 11. The balloon is then advanced until the extra distal wire exit 11 reaches the bifurcation and prohibits any further advancement. However, an alternate sequence of steps is possible depending on the individual situation and types of catheter configuration used. It may be possible to partially or totally pre-load the extra wire into the extra wire channel and advance it through the extra distal wire exit with the application catheter already inside the patient and/or coronary arteries. One or more radiopaque markers make the location of the extra distal wire exit 11 visible to the operator.

This procedure permits stable positioning of a balloon catheter within a bifurcated vessel. But, more importantly, it orients the extra distal wire 11 exit automatically into the direction of the opening to the main artery, prohibiting any

further rotation of the balloon, which may carry a stent or other therapeutic means. Thereby, stents with oblique ends may be placed precisely into sidebranches.

For stable balloon placement in ostial lesions, pre-positioning of the extra guidewire 15 is not necessary. In these cases, the extra distal wire channel 14 may be pre-loaded and the extra guidewire 15 may be advanced through the extra distal wire exit 11 once the balloon is approaching the target ostium. For ostial lesions, more than one extra distal wire channel 14 may be helpful and the wires used need no steerability but rather an atraumatic distal configuration and floppy property, e.g. mini-pigtail shape (see Figure 4A.), super-elasticity (e.g. use of the material Nitinol).

The longitudinal axis of sidebranches are almost never perpendicular to the longitudinal axis of the vessel from which they are taking off. Therefore, the current stent configurations of cylindrical tubular shape with the cross-sectional plane of the ends of the stent being perpendicular to the longitudinal axis of the cylinder stent are inadequate. This configuration does not permit full stent coverage of the ostium of a sidebranch, as there is always the risk of protrusion of one edge of the end of the stent into the lumen of the main artery, as shown in Figure 3B. Stents with at least one oblique end are needed to better adapt to bifurcational anatomies, in particular the vessel takeoff angles.

A stent is described, where one end of the stent cylinder is cut in a plane which is non perpendicular to the longitudinal axis of the stent, (i.e. oblique), preferentially in an angle of 80 to 45 degrees to the longitudinal axis of the stent (or 10 to 45 degrees to the axis perpendicular to the longitudinal axis of the stent), as seen in Figure 2C. This configuration is defined by a minimum and maximum length, 61 and 64 respectively, of a stent. This is compared to a prior art stent of Figure 2B wherein the cross-sectional plane of the stent end 51 is perpendicular to the longitudinal axis 50 of the stent.

Placement and use of the oblique ended stent is achieved

if the stent carrying instrument, e.g. balloon catheter, can be directed so that the long and short sides of the stent are placed correctly in the ostium. This can be accomplished by the self-orienting catheter with an extra distal wire exit 11 of the present invention. The bifurcational stent will he mounted on the balloon such that the shortest portion of the oblique end is closest to the extra distal wire exit 11. As seen in Figure 3C, an oblique ended stent 90 of the present invention covers a lesion 92 and is placed properly in the bifurcated artery.

Equivalent elements and steps can be substituted for the elements and steps employed in this invention to obtain substantially the same results in substantially the same way.

Claims

1. An improved dilatation catheter having a pliable shaft, a wire channel formed in the shaft, an inflation means for expanding body vessels surrounding the shaft and a guidewire for inserting into the wire channel, the improvement comprising:

a distal first guidewire exit of the shaft located distal to the inflation means, and

at least one additional proximally located guidewire exit located along a portion of the inflation means.

2. The dilatation catheter of claim 1, further comprising a tubular expandable stent surrounding the inflation means, the stent having a cross-sectional plane of at least one end being non-perpendicular to a longitudinal axis of the tubular stent.

3. The dilatation catheter of claim 2, wherein the angle of the cross-sectional plane of at least one end of the stent to the longitudinal plane of the stent is between 45 and 80 degrees.

4. The dilatation catheter of claim 2, wherein the inflation means is an inflatable balloon.

5. The dilatation catheter of claim 4, wherein the stent is mounted on a portion of the balloon which is distal to the at least one additional proximally located guidewire exit such that an extension of the longitudinal axis of a minimum length of the stent is pointing to the at least one additionally proximally located guidewire exit.

6. The dilatation catheter of claim 4, wherein the at least one additional proximally located guidewire exit along the inflatable balloon is a distal exit of an at least one positioning guidewire channel, the at least one positioning guidewire channel having a proximal exit through a proximal end of the catheter shaft.

7. The dilatation catheter of claim 4, wherein the at least one additional proximally located guidewire exit along the inflatable balloon is a distal exit of the at least one positioning guidewire channel, the at least one positioning guidewire channel having a proximal exit through a side-hole formed in a proximal end of an inflatable portion of the balloon.

8. The dilatation catheter of claim 4, wherein the at least one additional proximally located guidewire exit along the inflatable balloon is an intermediately positioned exit along a channel mounted outside the inflatable balloon, a regular guidewire and a positioning guidewire both inserting through the channel for at least a segment of the channel.

9. The dilatation catheter of claim 6, wherein the wire channel is in fluid connection with the at least one additional proximally located guidewire exit along the catheter shaft.

10. The dilatation catheter of claim 7, wherein the wire channel is in fluid connection with the at least one additional proximally located guidewire exit along the inflatable portion of the balloon.

11. The dilatation catheter of claim 2, wherein the tubular stent has at least one oblique end, the oblique end formed by a circumferentially extending ring like band when the stent is in an expanded state, the band having an axis of its cross-sectional plane that is non-perpendicular to the longitudinal axis of the tubular stent.

12. The dilatation catheter of claim 11, wherein the oblique end of the stent is formed by a series of closed loop elements aligned circumferentially to form a tubular segment, wherein at least two such loops have different lengths of their longitudinal axis.

13. The dilatation catheter of claim 11, wherein the oblique end of the stent has two ends and is formed by sinusoidally bent wire like material extending circumferentially, the two ends of the sinusoidal bent wire being closed around a cylinder to form a tubular segment, a cross-sectional plane of such tubular segment being non-perpendicular to the longitudinal axis of the stent, and wherein the sinusoidal bent wire is being transformed upon expansion of the tubular segment into an essentially ring like structure, wherein all angles in a circumferential axis of the formerly sinusoidal bent wire are between 135 and 180 degrees.

14. A dilatation catheter of claim 1, further comprising a positioning wire having a distal tip of a pigtail configuration of at least one full 360 degree loop.

15. A dilatation catheter of claim 1, further comprising a positioning wire having a distal tip of a pigtail configuration of almost one full 360 degree loop.

16, A dilatation catheter of claim 1, further comprising a positioning wire having a distal tip segment of super-elastic property and radiopacity.

17. The dilatation catheter of claim 1, wherein the at least one proximally located guidewire exit along the inflatable portion of the balloon is marked by at least one radiopaque marker element on the balloon.

18. The dilatation catheter of claim 1, wherein the at least one proximally located guidewire exit along the inflatable portion of the balloon is marked by at least one radiopaque marker element on the catheter shaft.

FIG. 1A

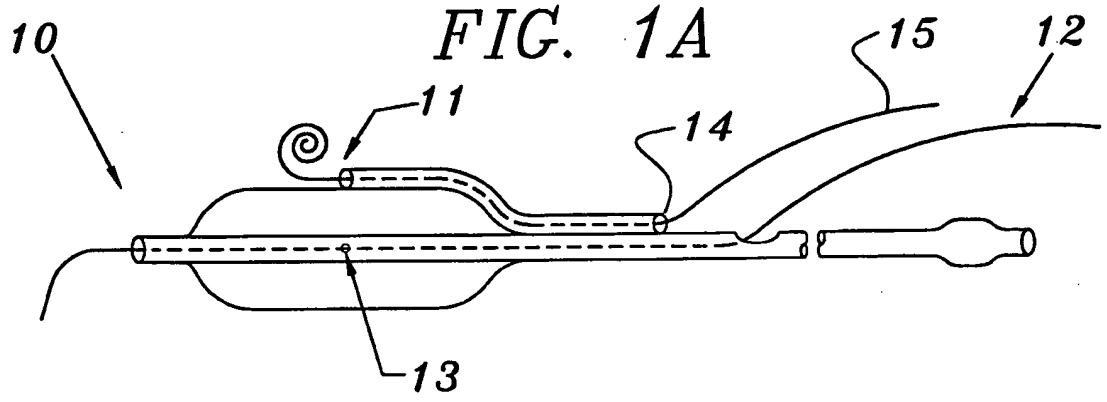


FIG. 1B

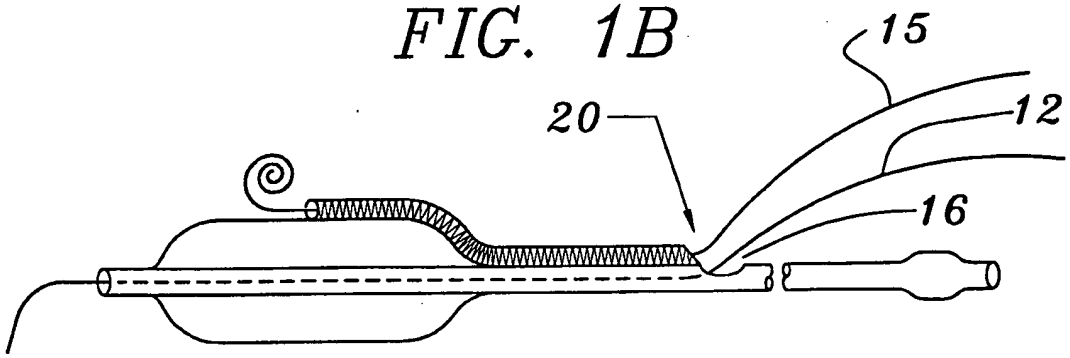


FIG. 1C

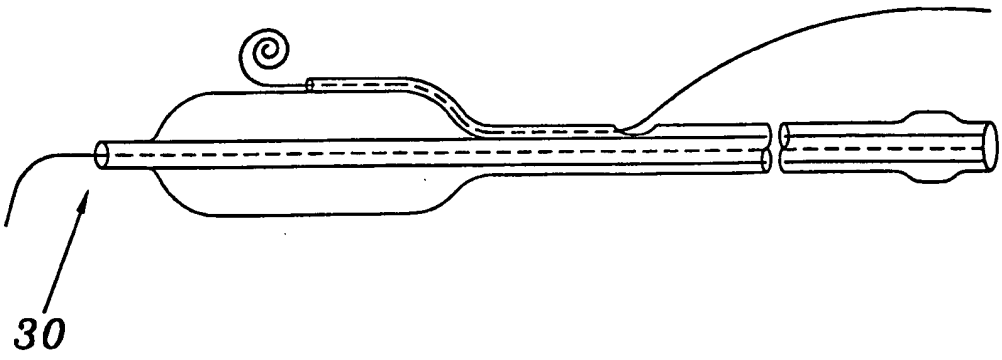


FIG. 1D

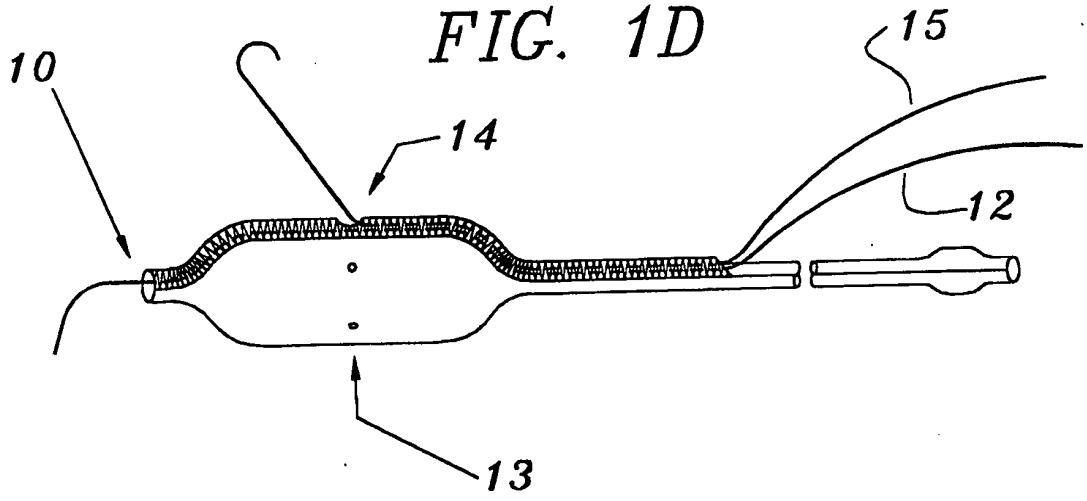


FIG. 2A

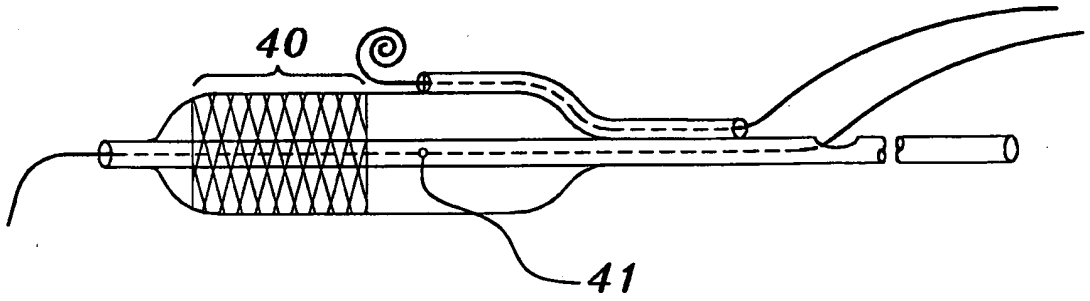


FIG. 2B

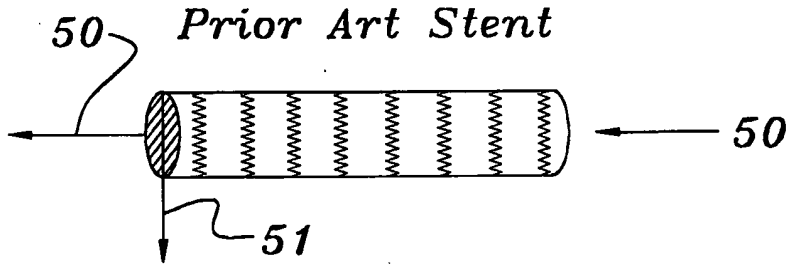


FIG. 2C

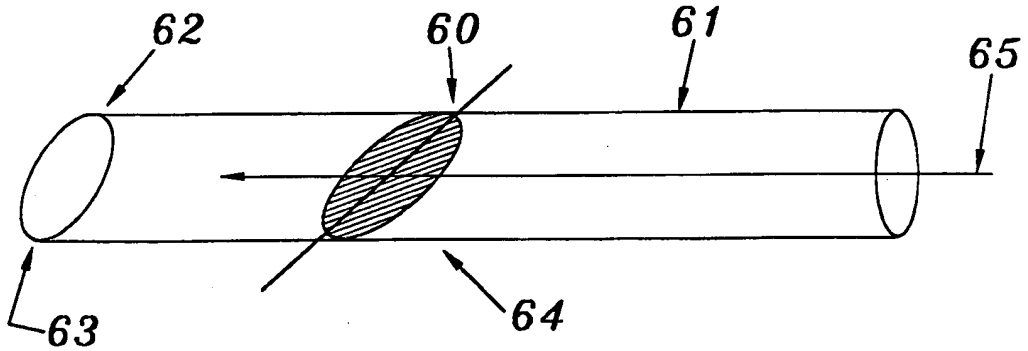


FIG. 3A

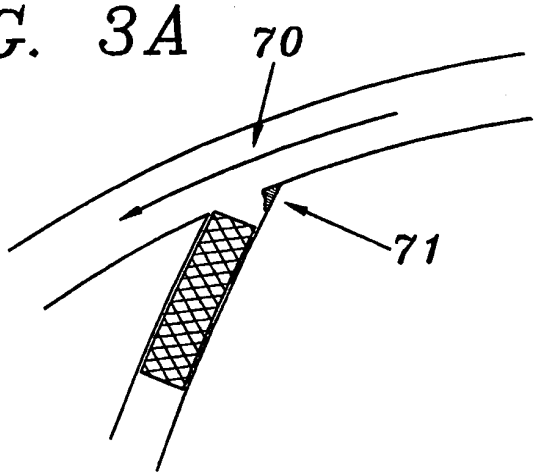


FIG. 3B

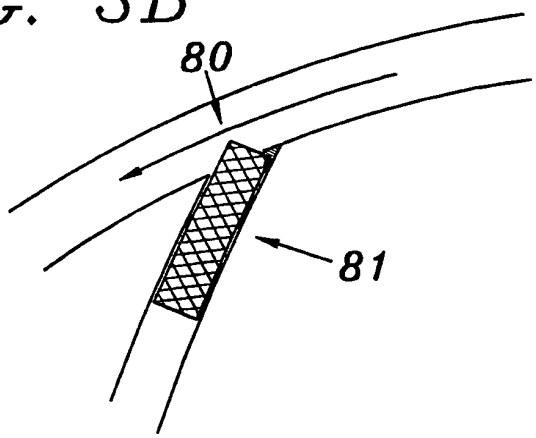


FIG. 3C

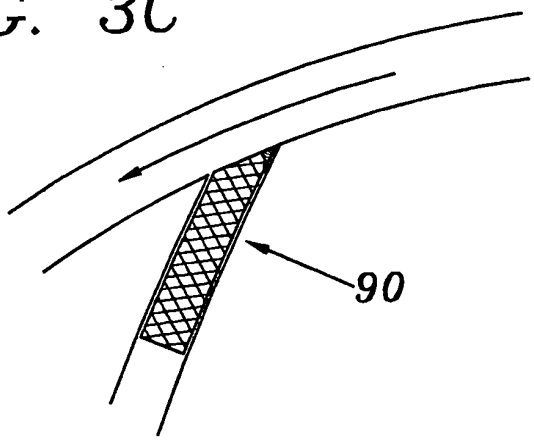


FIG. 4A

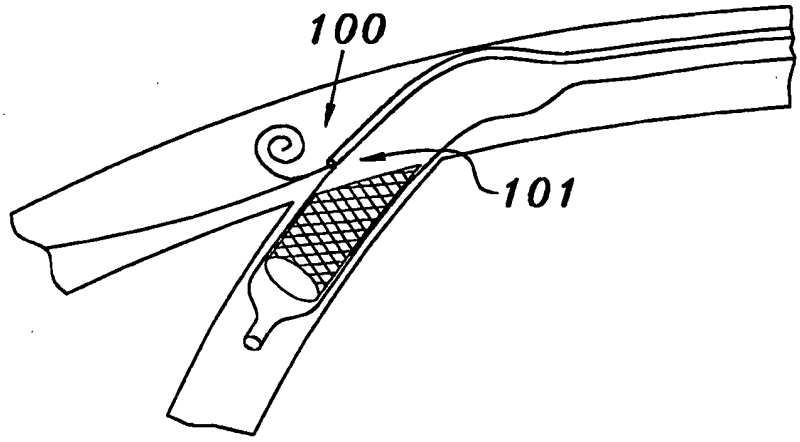


FIG. 4B

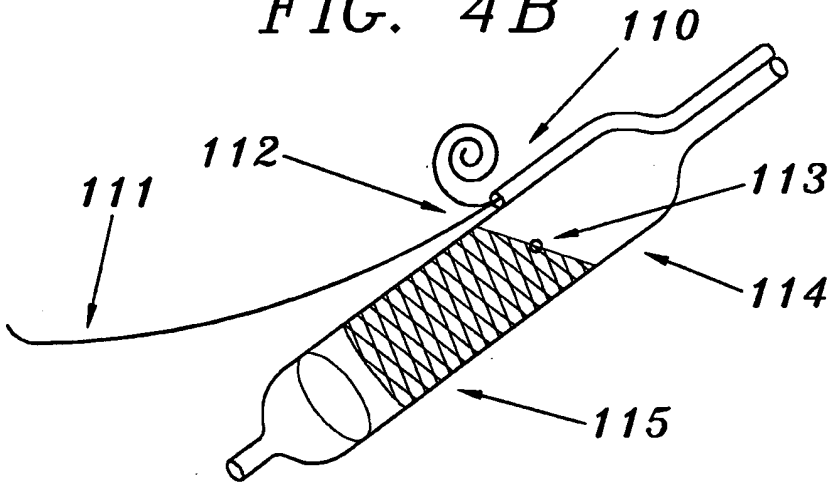
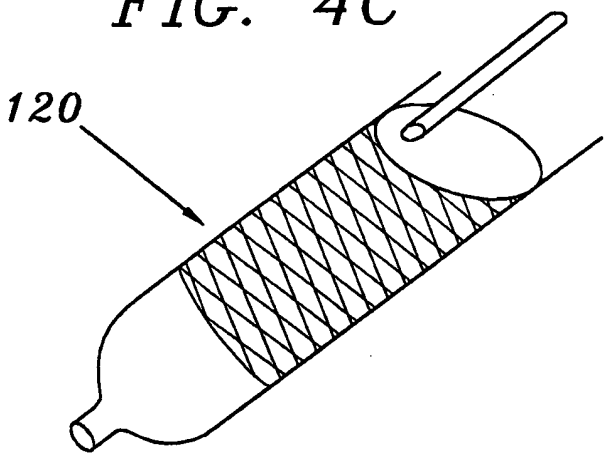


FIG. 4C



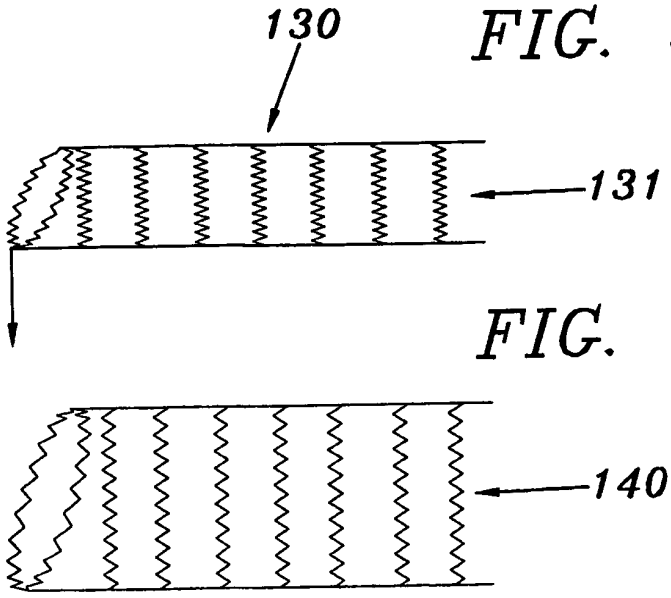
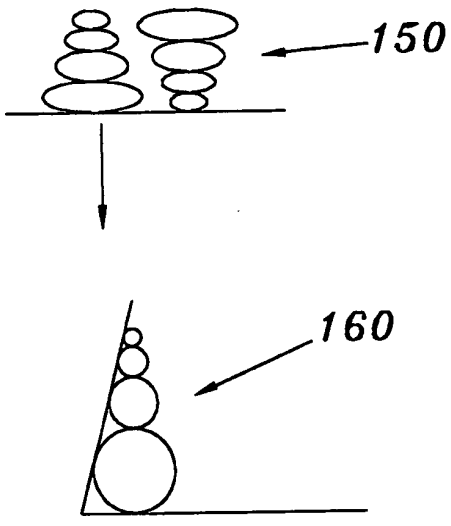


FIG. $5A_1$

FIG. $5A_2$

FIG. $5B_1$

FIG. $5C_1$



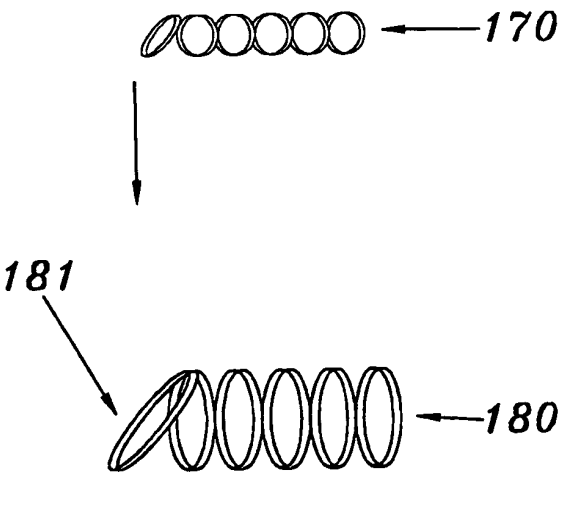


FIG. $5B_2$

FIG. $5C_2$

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/IB 98/01296

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 34580 A (DIBIE) 7 November 1996 see abstract; figures	1
A	WO 96 36269 A (EDOGA) 21 November 1996 see figures 14,15	1
A	WO 96 41592 A (BARD GALWAY LIMITED) 27 December 1996 see abstract; figures	1
A	US 4 983 167 A (SAHOTA) 8 January 1991 see abstract; figures	1
A	US 5 263 932 A (JANG) 23 November 1993 see the whole document	1

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☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
14 December 1998	22/12/1998

Name and mailing address of the ISA	Authorized officer
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1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna[illegible]l Application No
PCT/IB 98/01296

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9634580 A	07-11-1996	FR 2733682 A	08-11-1996
		AU 5345096 A	21-11-1996
		CA 2220141 A	07-11-1996
WO 9636269 A	21-11-1996	US 5591228 A	07-01-1997
		US 5662614 A	02-09-1997
		AU 5918996 A	29-11-1996
		US 5746766 A	05-05-1998
WO 9641592 A	27-12-1996	IT B0950292 A	09-12-1996
		IT B0960201 A	15-10-1997
		IT B0960202 A	15-10-1997
		AU 5675196 A	09-01-1997
		AU 5776696 A	09-01-1997
		CA 2223479 A	27-12-1996
		CA 2223502 A	27-12-1996
		EP 0830108 A	25-03-1998
		EP 0830109 A	25-03-1998
		WO 9641591 A	27-12-1996
US 4983167 A	08-01-1991	US 5019042 A	28-05-1991
		US 5147377 A	15-09-1992
		US 5090958 A	25-02-1992
		US 5160321 A	03-11-1992
US 5263932 A	23-11-1993	EP 0634942 A	25-01-1995
		JP 7506025 T	06-07-1995
		WO 9320880 A	28-10-1993
		US 5462530 A	31-10-1995